AMENDMENT TO MR. TAUZIN'S AMENDMENT

OFFERED BY M.s Capps

(Page & line nos. refer to Chairman's Mark of June 17, 2003)

Amend section 303(b) (relating to reform of average wholesale price methodology for outpatient prescription drugs covered under part B) [page 150, beginning on line 11 through page 172, line 21] and insert the following:

(b) PAYMENT REFORM.—

(1) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended to read as follows:

"(o) PAYMENT FOR DRUGS AND BIOLOGICALS.—

"(1) GENERAL RULE.—If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological shall be based on the following:

"(A) MULTI-SOURCE (GENERIC) DRUGS.—In the case of a drug or biological that meets the requirements for a multi-source drug under subclauses (I) and (II) of section 1927(k)(7)(A)(i), 115 percent of the volume-weighted median average acquisition price for any drug or biological covered under the same medicare HCPCS code.

"(B) SINGLE SOURCE (BRAND) DRUGS AND BIOLOGICALS.—In the case of a drug or biological that meets the requirements for a single source drug under section 1927(k)(7)(A)(iv), 115 percent of the average acquisition price for the drug or biological.

"(C) ACCESS EXCEPTION.—The Secretary may modify the rate otherwise applicable in order to assure

access to necessary drugs and biologicals in the case of sole community providers in rural and other areas where the providers are not reasonably able to obtain the drugs and biologicals at the payment rates otherwise applicable. Such modification shall not result in a change of more than 15 percent of the rate otherwise applicable.

"(D) DATA-RELATED EXCEPTION.—If the Secretary determines that there is insufficient data available with respect to compute an average acquisition price for a drug or biological for a quarter or that, because of a significant change in price from quarter-to-quarter, the available data on the average acquisition price does not accurately reflect the actual, current acquisition cost for the drug or biological, the Secretary may substitute for the quarters involved an appropriate payment for the drug or biological for such average acquisition price.

"(E) APPLICATION OF NDC CODES.—If the Secretary determines that it is appropriate to provide for payment under this subsection using national drug code (NDC) instead of HCPCS codes, in applying subparagraph (A) the reference to the same HCPCS code shall be deemed a reference to the appropriate national drug codes for those drugs or biologicals that are therapeutically and pharmaceutically equivalent and bioequivalent (as defined for purposes of section 1927(k)(7)(A)).

"(2) DEFINITION OF AVERAGE ACQUISITION PRICE.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'average acquisition price' means, with respect to a drug or biological and with respect to each dosage form and strength of the drug or biological product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package), the average of all final sales prices charged by the manufacturer of the drug or biological product in the United States, excluding sales exempt from in-

clusion in the calculation of best price under section 1927(c)(1)(C) (other than under clause (ii)(III) of such section) and excluding sales subject to a rebate under section 1927, as reported under paragraph (3).

"(B) NET PRICE.—Such average acquisition price shall be calculated net of all of the following (as estimated by the Secretary):

"(i) Volume discounts.

"(ii) Prompt pay discounts and cash discounts.

"(iii) Charge-backs.

"(iv) Short-dated product discounts (for spoilage and other factors).

"(v) Free goods and services.

"(vi) Rebates.

"(vii) All other price concessions provided by the drug manufacturer.

The Secretary may make subsequent adjustments in such average acquisition price to take into account updated information and differences between the price previously estimated and the actual average acquisition price.

"(C) WEIGHTING.—The average of all final sales prices described in subparagraph (A) shall be determined by dividing—

"(i) the sum of all final prices charged by the manufacturer (net of the adjustments made under subparagraph (B)) for sales in the period involved that are included in subparagraph (A) for the drug or biological, by

"(ii) the total number of units of such sales in the period.

"(D) DISTRIBUTION OF REPORTS.—The Secretary shall promptly distribute applicable payment rates under this subsection to carriers and fiscal intermediaries and other contractors that make payment for

drugs and biologicals under this section in order to apply a uniform reimbursement rate under this section.

"(3) PRICE REPORTING REQUIREMENT.—

"(A) IN GENERAL.—As a condition for payment for any drug or biological of a manufacturer under this subsection, the manufacturer of the drug or biological shall—

"(i) report, on a quarterly basis, to the Secretary (or the Secretary's designee) the manufacturer's average acquisition price and the information required under subparagraph (C) for all drugs and biologicals of the manufacturer by national drug code (NDC);

"(ii) maintain such records (in written or electronic form) regarding such sales and prices for all such drugs and biologicals as may be necessary to audit the information so reported or required to be reported; and

"(iii) provide the Secretary with access to such records in order to permit the Secretary to audit information so reported or required to be reported.

"(B) PENALTIES.—The provisions of section 1927(b)(3)(C) shall apply with respect to the reporting of information under subparagraph (A) in the same manner as it applies to the reporting of information under section 1927(b)(3)(A), except that the reference in clause (i) of such section to $10,000 is deemed a reference to $100,000 and any reference to a suspension of an agreement is deemed a reference to a suspension of payment for the drug or biological involved under this part. The Secretary shall promptly refer to the Inspector General of the Department of Health and Human Services and, if appropriate, to appropriate officials in the Department of Justice cases in which the Secretary becomes aware of a false price representation made in the information submitted under this paragraph.

"(5) PAYMENT REQUIRED ON AN ASSIGNMENT-RELATED BASIS.—

"(A) IN GENERAL.—Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

"(B) APPLICATION OF ENFORCEMENT PROVISIONS.—The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C).".

(2) EFFECTIVE DATE.—Subject to subsection (b)(2), the amendment made by paragraph (1) shall apply to drugs and biologicals furnished on or after January 1, 2004.

(b) STUDY OF PAYMENTS FOR BLOOD CLOTTING FACTORS AND OTHER BIOLOGICALS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall provide for a study of the appropriateness of the medicare payment methodology for blood clotting factors and other biologicals under part B of title XVIII of the Social Security Act. Not later than 9 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on such study and shall include in such report recommendations regarding whether to apply the payment methodology provided under the amendment made by subsection (a)(1) and alternative recommendations for appropriate dispensing fees.

(2) DELAY IN EFFECTIVE DATE.—The amendment made by subsection (a)(1) shall not apply to blood clotting factors furnished before the first day of the first calendar year that begins at least 6 months after the date the report under paragraph (1) has been submitted to the Congress.

"(C) FORM OF REPORTING.—Information required to be reported under subparagraph (A)(i) shall be reported in a form and manner specified by the Secretary. The information required to be reported shall include the identification of the generic name of the drug or biological and its brand name (if any), the national drug code (NDC) and the HCPCS code assigned to the drug or biological, the dosage form, strength, volume, and package size involved. The information for a quarter shall be submitted not later than 30 days after the end of the quarter. The information shall be accompanied by a written and signed certification by an officer of the manufacturer attesting to the accuracy of the information reported. Such information shall include updated information on the net price realized (taking into account rebates and other amounts affecting net price), regardless of the period for which such a rebate or other adjustment in net price might have been earned.

"(D) AUDITING.—The Secretary shall audit on a periodic basis information reported or required to be reported under this paragraph. The Secretary may conduct such independent price gathering activities, such as surveys and review of published catalog information or other transactional information, as may be appropriate to verify the accuracy of the information reported.

"(4) DISPENSING FEE.—If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary shall pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. Such a dispensing fee shall be subject to adjustment from year to year based upon changes in the consumer price index over time and may be adjusted as the Secretary determines to be appropriate to reflect differences in the costs of dispensing different drugs and biologicals.